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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,577	06/28/2001	Shigefumi Sakai	210354US0	2545
22850	7590	02/23/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,577

Applicant(s)

SAKAI ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "under conditions sufficient to provide droplets" in claim 33 renders the claim vague and indefinite, as it is not clear what these conditions are limited to. For example, does the limitation refer to the type of cooling oil, the temperature thereof, or the vibration frequency applied to the orifice?

The term "analog" in claim 45 renders the claim vague and indefinite, as the metes and bounds of the scope of the limitation are not clear.

The remaining claims are rejected as they depend on indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-43 and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrieu et al. (US 5961990) ("Delrieu").

The claimed invention in Claim 33 is a composition comprising a hydrogel particles dispersed in an aqueous medium wherein each of said hydrogel particles comprises a non-crosslinked hydrogel having an oil component dispersed therein, wherein said hydrogel particles are prepared by a process comprising: providing an emulsion or dispersion of components comprising a non-crosslinked hydrogel-forming polymer, the oil component, and water; and discharging said emulsion or dispersion through an orifice into a cooling oil.

The present claims are product-by-process claims. The court in In re Thorpe held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). The court in In re Brown also held, "when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-

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process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.” See 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). In this case, if a prior art teaches the same or obvious composition having the recited physical properties of the claimed composition, a rejection is proper. The requirement for the physical property limitation of the composition here means that the prior art composition should comprise hydrogel particles comprising a non-crosslinked hydrogel having an oil component dispersed therein, wherein the hydrogel particles are dispersed in an aqueous medium. The limitations in the dependent claims that are directed to the physical properties of the hydrogel particles, such as droplet shape and size, breaking intensity, ratio of longest/shortest diameters, etc. will be also considered. See instant claims 37, 39-49. However, the limitation on the process of making the claimed hydrogel-containing composition as recited in the base claim, Claim 33, is directed to the process of making the composition which is viewed not patentably distinct from the prior art cited herein. Although examiner has not given weight to the process limitations in Claims 33-36, and 38, the prior art method of making hydrogel particles is discussed below.

Delrieu discloses agar gel beads of an average diameter of 2 mm comprising lipophilic beta-carotene dispersed in water. See Example 7; instant claims 33, 39, 40, and 46. The reference teaches that the particles are formed by injecting the agar solution/beta-carotene mixture through a needle into liquid paraffin oil at 5 °C, a temperature below the agar gelling point. See instant claim 38. See col. 4, line 62 – col. 5, line 18 for the method of making the beads. The resulting agar beads are then

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incorporated into cosmetic compositions such as creams, gels and lotions (an aqueous composition). See col. 16, lines 53 – 58; instant claim 49. While the applications of vibration to the apparatus as recited in instant claims 34-36 are process limitations, it is nevertheless noted that Delrieu teaches to control the size of the beads by agitation of the oil bath. Col. 13, line 65 – col. 14, line 6; Example 10. See instant claims 33, 34-36. The reference teaches restraining polymers that are dispersed in the agar gel, which is viewed as polymer emulsifying-dispersing agents, which include quaternized polysaccharides. See col. 4, lines 6 – 20; col. 8, line 18 – col. 10, line 5. See instant claims 41 and 43. The reference teaches that at least 80 % of the particles are within the desired average particle size range of 0.05-10 mm. See col. 5, lines 42 – 59.

It is viewed that the prior art agar beads that meet the claimed limitations of instant claim 33 inherently has the same breaking intensity and gel strength of as recited in instant claims 47 and 48, respectively. See col. 13, lines 7 – 26 which teaches that the hardness of the gel beads are controlled so that the beads are soft and crushable upon contact with the skin.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu as applied to claims 33-43 and 46-49 as above, and further in view of Tsaur et al. (US 5726138).

While Delrieu, discussed above, teaches dermatological actives suitable for the invention in col. 10, lines 6 – col. 11, line 11, the reference fails to teach solid fatty actives or ceramides.

Tsaur discloses aqueous compositions comprising hydrogel particles comprising water-insoluble skin benefit ingredients entrapped therein. See col. 2, line 63 – col. 3, line 60. Tsaur teaches that the suitable benefit agents include specific waxes, hydrocarbons, cholesterol ester ceramides, and pseudoceramides. See col. 8, lines 5 – 58; Examples 8-10; see instant claims 44 and 45. These actives are taught to provide protection, moisture or conditioning effect to the skin. See *Id.* The reference teaches that the benefit agent is dispersed in the hydrogel-forming polymers before the formation into hydrogel particles. See col. 4, lines 28 – 44; instant claim 41. Using surfactants in mixing the benefit agent and the hydrogel-forming polymer solution is also disclosed in col. 9, lines 6 – 24. See instant claim 41. The reference teaches using acrylic polymers such as modified polysaccharides, cationic modified cellulose, Carbopol by B.F. Goodrich, polyvinyl alcohol, which meet the “polymer emulsifying or dispersing agent” limitation of instant claim 43. See col. 7, lines 48-65. It is also noted that modified polysaccharides and cationic modified cellulose are used in Delrieu as restraining polymers. The reference teaches an aqueous lotion composition with petrolatum, a solid fatty substance with m.p. 38-60°C, contained in a hydrogel particle comprising chitosan, a non-crosslinked, thermal gelatin. See Example 15; instant claims 42, 44, and 49. The diameter of the petrolatum hydrogel particles there is deemed to be 200 microns. See instant claim 37. Tsaur teaches to use two types of

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polymers to form hydrogel, wherein the first polymer may be thermal gelatin, such as agar or gelatins; and the second polymer is selected depending on the desired gel strength. See col. 5, line 56 – col. 6, line 22; instant claim 47. The reference further teaches that the gel strength can be manipulated by controlling the amounts of the two polymers and the particle size. See col. 7, lines 33 – 40; col. 17, lines 44 – 57; instant claim 47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions comprising agar beads of Delrieu by substituting the actives with the Tsaur wax or ceramides along with surfactants, as motivated by the collective teachings of the references, because 1) Delrieu teaches using dermatologically active substances to provide prophylactic and treatment effect to the skin; and 2) Tsaur teaches that the disclosed benefit agents therein can protect, moisturize or condition the skin after being deposited from the aqueous composition.

The skilled artisan would have had a reasonable expectation of successfully producing a cosmetic composition which provides the controlled-release of the cosmetic wax or ceramide active ingredients because both Delrieu and Tsaur are teach hydrogel particles comprising oily active ingredients dispersed therein which are then incorporated into aqueous medium.

Response to Arguments

Applicant's arguments with respect to claims 33-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER